

UNIVERSITY OF
ROCHESTER
MEDICAL CENTER

STRONG MEMORIAL HOSPITAL
SCHOOL OF MEDICINE AND DENTISTRY
SCHOOL OF NURSING

DEPARTMENT OF OBSTETRICS-GYNECOLOGY
REPRODUCTIVE ENDOCRINOLOGY/
INFERTILITY UNIT

2000 '00 JAN -5 P1:59

December 20, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5360 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket # 97N-484S, Suitability Determination for Donors of Human Cellular and Tissue-Based Products

Sirs:

I am writing regarding the above. I have been involved with donor oocytes in vitro fertilization (IVF) both here and elsewhere for about 10 years, and currently direct an IVF program that performs about 10 or 15 cycles involving oocyte donation each year. Although this represents a relatively small proportion of our total IVF caseload, we consider this to be an important service, if only because the recipients in such cases have no viable alternative to achieving pregnancy. All of our oocyte donors are, of course, extensively screened prior to proceeding with an attempt at donor oocyte IVF, even when they are related to the recipient.

The proposal to quarantine embryos derived from donor oocytes to allow for additional donor testing 6 months following retrieval, of course, would require embryo cryopreservation. We have had success rates (successes defined as pregnancies resulting in live births) of better than 50% per oocyte retrieval for many years in cases using oocyte donors, whereas our success rates for using frozen embryos have been generally well less than half of this. Most other programs have had a similar experience. These numbers, of course, relate to the adverse effects of embryo cryopreservation on the ability to achieve viable pregnancy. Accordingly, the proposal in question would substantially increase costs for patients while at the same time dramatically compromising outcomes. Furthermore, unnecessary invasive procedures, i.e. oocyte retrievals would undoubtedly need to be carried out, since unsuccessful (i.e., not pregnant) recipients of embryos derived from donor oocytes are often likely to want to try again. Though rare, women have died from complications associated with oocyte retrievals. In contrast, I am not aware of a single case of an infectious disease ever being transmitted from an oocyte donor to a recipient.

In summary, the described proposal to quarantine embryos derived from donor oocytes is absolutely unacceptable, and would be harmful to both donors and recipients involved.

Sincerely,

William R. Phipps
William R. Phipps, M.D.

Director, Strong Infertility and IVF Program

97N 484S

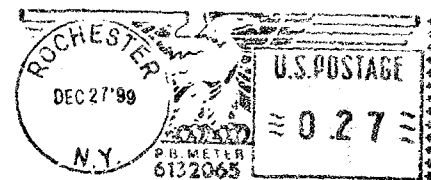
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TEMP-RETURN SERVICE REQUESTED

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